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cc: kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on 7-Benzofuranol, 2,3-dihydro-2,2-dimethyl- (CAS# 1563-66-2)

(Submitted via Internet 6/28/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and natalie_rutherford@fmc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 7-Benzofuranol, 2,3-dihydro-2,2-dimethyl- (CAS# 1563-66-2).

Rather than providing a test plan and robust summary, sponsor FMC Corporation submitted only a brief letter for 7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-, commonly known as carbofuran. This letter states that carbofuran is a pesticide regulated under FIFRA, and that the company has generated and provided to EPA a large amount of health and safety data as part of its registration and re-registration of this chemical under FIFRA. The company further states that the scope of these data extends well beyond the requirements of the HPV Challenge, and hence that it believes it has met its obligation under the latter program.

While we fully expect that the company's description of the data available for this chemical is accurate, we do not believe the company has yet met the obligations, as set forth as part of the company's commitment to sponsor this chemical under the HPV Challenge. A primary purpose of the Challenge, as a core element of EPA's Chemical Right-to-Know Initiative, is to make screening-level data characterizing the hazard potential of HPV chemicals publicly available. A critical step in fulfilling that purpose is the part of the commitment made by sponsors to provide and submit robust summaries of available (as well as any newly generated) data that address each of the SIDS endpoints. Indeed, these robust summaries are the primary means by which data collected and developed through the program will be made publicly available.

As EPA stated in the December 26, 2000, Federal Register notice, "Data Collection and Development on High Production Volume (HPV) Chemicals the HPV Challenge," which described sponsors' obligations (see www.epa.gov/chemrtk/ts42213.htm):

The following are expected to be provided by those wishing to participate as viable commitment sponsors in the voluntary HPV Challenge Program:

... 3. A ``Robust Summary.'' A ``robust summary'' prepared in a standardized electronic format for each existing and new study. These summaries will be submitted to EPA and will be posted on the Agency's ChemRTK web site to ensure public access to detailed synopses of the studies for the SIDS endpoints. Guidance on the content/format of a ``robust'' summary can be found on the ChemRTK web site (Ref. 6).

In its original letter committing to sponsor this and a number of other HPV chemicals, dated March 10, 1999 (see www.epa.gov/chemrtk/c01302.htm), FMC

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acknowledged its obligations as a sponsor:

FMC recognizes that sponsorship entails assembling and reviewing available test data, developing and providing test plans for each of the sponsored chemicals, and, where needed, conducting additional testing in the time frame established by the Challenge program. The information and data we provide under the HPV Challenge Program will be made publicly available.

In its letter, FMC also indicated that it expects EPA to issue its Interim Registration Eligibility Decision (IRED) for public review and comment "in the near future." Even were this interim decision document a sufficient vehicle for making hazard data on carbofuran publicly available (and we do not consider it to be so), we note that EPA has indicated that its IRED will not be issued until March, 2006 ? well after the 2005 date by which all HPV Challenge data are to be made public (see www.epa.gov/pesticides/reregistration/status.htm).

In summary, as indicated in its letter, FMC Corporation is the holder of data on carbofuran sufficient to meet the requirements of the HPV Challenge, and hence the company has access to the studies needed to satisfy the requirements of the Challenge. As a ? indeed, the sole ? sponsor of this chemical under the Challenge, the company has a clear obligation to develop robust summaries of these data and submit them so they can be made public available.

Thank you for this opportunity to comment.

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